maine standards COMPANY LLC

SEP 29 2006

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K062501."

Submitter: Maine Standards Company
Address: 765 Roosevelt Trail
Windham, ME 04062
Telephone: 207-892-1300
Fax: 207-892-2266
Contact: Holly A. Cressman, Mgr. QA/RA

Summary prepared on: August 16, 2006

Device classification name: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
Device description: Quality control material (assayed and unassayed)
Proprietary Name: VALIDATE® Thyroid Calibration Verification Test Set
Regulation Number: 21 CFR 862.1660
Product Code: JJY
Regulatory Class: Class I

Predicate Device:
DOCUMENT Thyroid CAL•VER (K992034), Microgenics Corp, Fremont, CA

Device description: VALIDATE Thyroid Calibration Verification Test Sets are human serum based calibration verification / linearity materials containing multiple levels used to establish the relationship between theoretical operation and actual performance of the included analytes. Each test set consists of one bottle each of six (6) levels including zero. Each bottle of Levels 0 through 5 contains 3.0 milliliters. There exists a linear relationship among each set of solutions.

Intended use: The VALIDATE Thyroid Calibration Verification Test Set solutions are for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in chemistry systems for the following analytes: Triiodothyronine (T3), Thyroxine (T4), human Thyroid Stimulating Hormone (TSH), and Cortisol. VALIDATE Thyroid Calibration Verification Test Set solutions are not intended for use as routine quality control materials or as calibration materials.

Summary:
The information provided in this pre-market notification demonstrates that the performance of VALIDATE Thyroid Calibration Verification Test Sets is substantially equivalent in form and function to the predicate device for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Holly Cressman, QA/RA Manager
Maine Standards Company, LLC
765 Roosevelt Trail
Windham, ME 04062

SEP 2 9 2006

Re: k062501
Trade/Device Name: VALIDATE® Thyroid Calibration Verification Test Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: August 22, 2006
Received: August 25, 2006

Dear Ms. Cressman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062501

Device Name: VALIDATE® Thyroid Calibration Verification Test Set

Indications For Use:

VALIDATE Thyroid Calibration Verification Test Set solutions are for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in chemistry systems for the following analytes: Triiodothyronine (T3), Thyroxine (T4), human Thyroid Stimulating Hormone (TSH), and Cortisol.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062501